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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,031	10/16/2001	Mirna Rapp	0843.0002	7920

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EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,031	RAPP, MIRNA	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *25-58* is/are allowed.

6)☐ Claim(s) *59-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of the Claims

The amendment and response filed July 21, 2004 has been entered and considered. Claims 59-73 have been added. Therefore, Claims 25-73 are pending and have been considered in this Office Action.

Rejections Withdrawn

The rejections of Claims 36, 53, and 57 under 35 U.S.C. 112, second paragraph are withdrawn in light of the amendments and response.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-68 and 70-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 59, 63, and 64 omit the limitation that the formulations contain a calcium salt. Upon reviewing the Specification, it appears that every reference to the formulation and the examples for making the formulation all contain calcium salts and

the Specification does not teach that the calcium salts may be omitted from the formulation of the invention. Therefore, the specification does not clearly disclose that the a formulation without calcium salts was contemplated at the time of the invention (see MPEP 2163.05(I) with regard to Omission of limitations).

Claims 60-62 and 65-68 are rejected because they depend from Claim 59 yet do not correct its deficiencies.

Claim 62 is rejected because the specification does not support the claimed genus of water-soluble sugars, sugar substitutes, and biological transport substitutes (see MPEP 2163.05 (I) for discussion of addition of generic claim). The ordinary artisan could not predict that the genus of water soluble sugars and sugar substitutes were contemplated by the inventor based on the disclosure of using "sugars and sugar alcohols such as saccharose, lactose or mannitol, which have good bio-tolerance" (see p. 6). Moreover, the specification does not appear to teach using "biological transport substitutes".

Claim 68 is rejected because the specification does not appear to disclose that the granulates are provided with an "outer barrier layer".

Claim 70 is rejected for reciting a temperature range limitation that does not appear to be disclosed in the Specification as filed (see MPEP 2163.05 (III)). The only reference to temperature in the Specification appears to be in the examples where the step of forming the flowable solid granulates was performed at a product temperature of 30°C. The specification does not clearly disclose that the inventor considered the temperature range to be part of the invention.

Claims 71-73 are rejected since they depend from Claim 70 yet do not correct its deficiencies.

35 U.S.C. 135(b)—Rejection

Claims 59-73 are rejected under 35 U.S.C. 135(b) as not being made prior to one year from the date on which US 2002/0037323 was published under 35 U.S.C. 122(b). See *In re McGrew,* 120 F.3d 1236, 1238, 43 USPQ2d 1632,1635 (Fed. Cir. 1997) where the Court held that the application of 35 U.S.C. 135(b) is not limited to *inter partes* interference proceedings, but may be used as a basis for *ex parte* rejections.

Also, see In re Berger, 61, USPQ2d 1523 (CAFC 2002) and Berman v. Housey, 63, USPQ2d 1023 (CAFC 2002).

Claims 59-64, 66, and 68-69 of instant USSN 09/869,031 are drawn to fibrin adhesive formulations comprising solutions or suspensions of thrombin, and fibrinogen with FXIII in flowable solid granules prepared by drying the solutions in a fluidized bed apparatus and forming flowable solid granules with a particle size of 50-1000μm.

Claim 65 of instant USSN 09/869,031 adds that the ratio of thrombin to fibrinogen with factor XIII is 1:100 to 1:1000.

Claim 66 of USSN 09/869,031 narrows the range of granule size to 100-200μm.

Claims 1-6, 13, and 15 of US 2002/037323 are drawn to fibrin adhesive formulations comprising solutions or suspensions of thrombin, and fibrinogen with FXIII

in flowable solid granules prepared by drying the solutions in a fluidized bed apparatus and forming flowable solid granules with a particle size of 20-1000μm.

Claim 9 and 10 of US 2002/037323 adds that the ratio of thrombin to fibrinogen with factor XIII is 1:10 to 1:1000 and within the range of 1:502 to 1:200.

Claims 11 and 12 of US 2002/037323 narrow the range of granule size to 30-500μm and 40-200μm, respectively.

Claims 70-73 of USSN 09/869,031 are drawn to a process for producing a fibrin adhesive formulation containing thrombin, and fibrinogen with factor XIII in flowable solid granules comprising drying solutions of the thrombin, and the fibrinogen with factor XIII and forming the flowable solid granules at a product temperature not exceeding 50°C, wherein the granules have a particle size of 50-1000μm.

Claims 16-19 of US 2002/0037323 are drawn to a process for producing a fibrin adhesive formulation containing thrombin, and fibrinogen with factor XIII in flowable solid granules comprising drying solutions of the thrombin, and the fibrinogen with factor XIII and forming the flowable solid granules at a product temperature not exceeding 50°C, wherein the granules have a particle size of 20-1000μm.

The examiner acknowledges that the claimed ranges of particle size in the claims of the present application are slightly narrower than the claims of US 2002/0037323 and the claimed ratio of thrombin to fibrinogen with factor XIII of claim 65 of the present

Application differs slightly from that of claims 9 and 10 of US 2002/0037323. However, the subject matter of the claims of instant application USSN 09/869,031 is considered "substantially the same" as the published application US 2002/0037323 ("A claim which is the same as, or for the same *or substantially the same subject matter* as, a claim of an application published under section 122(b) of this title may be made in an application filed after the application is published only if the claim is made before 1 year after the date on which the application is published". (35 U.S.C. 135(b)(2) emphasis added).

Although the instant application USSN 09/869,031 was filed 10/16/2001; the instant claims drawn to fibrin adhesive formulations and methods of making the formulations identical to the claims of US 2002/0037323 , were filed 7/21/04. Therefore, the instant claims were not made prior to one year from the date which Claims 1-13 and 15 were published.

Claim Objections

Claim 66 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 66 provides the limitation, wherein the grain diameter of the granules is 50-1000μm, which is the same particle size recited in Claim 59, from which it depends. Correction is required.

Conclusions

Claims 59-73 are rejected. Claims 25-58 appear to be in condition for allowance for reasons of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
September 22, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER